JUN 2 6 2014

In accordance with 21 CFR 807.87 (h) and 21 CRF 807.92, the 510(k) summary for the Eminent Spine Black / Red Diamond Rattlesnake Lumbar Plating System is provided below.

Date Summary Prepared	June 11, 2014
Manufacturer/Distributor/Sponsor	Eminent Spine, LLC 7200 N 1-35 Building #1 Georgetown, TX 46037 Phone 512-868-5980 Fax 512-864-1462
510(k) Contact	Secure BioMed Evaluations Linda Braddon, Ph.D. 7828 Hickory Flat Highway Suite 120 Woodstock, GA 30188 770-837-2681 (direct) 855-MED-DEV1 (office) LGB@SecureBME.com
Trade Name	Black / Red Diamond Rattlesnake Lumbar Plating System
Common Name	Spinal intervertebral body fixation orthosis
Code –Classification	**KWQ** 21 CFR 888.3060: Class II
Predicate Devices	Medtronic Z-Plate (K922543) Acromed M-2 Plate (K972718) Nuvasive Lateral Plate System (K061789, K082070, K091071)
Predicate Device – 2 Hole Lateral Plate	Nuvasive Lateral Plate System K091071
Predicate – Anterior Plate	Medtronic Z-Plate (K922543) Acromed M-2 Plate (K972718)
Device Description	The *Eminent Spine Black / Red Diamond Rattlesnake Lumbar Plating System* consists of a variety of plates and screws. All components are fabricated and manufactured from titanium alloy 6AL-4V-ELI per ASTM F-136. The plates are manufactured in a variety of configurations with lengths of 21 to 33mm in a single level plate and 64 to 76mm in a two level plate. Additionally, the non-locking screws are provided in diameters of 5.5mm with lengths of 25 – 50mm. The responsible surgeon will determine the correct size of the implant in accordance with the size of the individual patient. The *Eminent Spine Black / Red Diamond Rattlesnake Lumbar Plating System* utilizes a variety of standard orthopedic instruments to assist in the placement of the devices.

Intended Use	The *Eminent Spine Black Diamond Rattlesnake Lumbar Plating System* is indicated for use via a lateral / anterolateral surgical approach above the great vessels in the treatment of the thoracolumbar spine (T1-L5). The *Eminent Spine Red Diamond Rattlesnake Lumbar Plating System* is indicated for use via an anterior surgical approach below the bifurcation of the great vessels in the treatment of the lumbosacral (L1-S1) spine. The Diamond Rattlesnake System is intended to provide temporary stabilization as an adjunct to fusion using a lateral approach in skeletally mature patients for the treatment of the following acute and chronic instabilities and deformities: degenerative disc disease (DDD, defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), pseudarthrosis, spondylolysis, spondylolisthesis, deformity (scoliosis, kyphosis, and or lordosis), spinal stenosis, fracture (including dislocation and subluxation), tumor, or failed previous spine surgery.
Technological Characteristics	As was established in this submission, the subject *Eminent Spine Black / Red Diamond Rattlesnake Lumbar Plating System* is substantially equivalent to the predicate systems in terms of design, intended use, material composition, function, and range of sizes.
Non-Clinical Performance Testing Conclusion	Nonclinical testing was performed to demonstrate that the *Eminent Spine Black / Red Diamond Rattlesnake Lumbar Plating System* is substantially equivalent to other predicate devices. The following testing was performed: • Static and dynamic axial compression testing per ASTM F1717 • Static torsion testing per ASTM F 1717 The results of these studies show that the subject *Eminent Spine Black / Red Diamond Rattlesnake Lumbar Plating System* meets or exceeds the performance of the predicate device, and the device was therefore found to be substantially equivalent.
Substantial Equivalence Summary (Conclusion)	The information presented demonstrates the substantial equivalency of the *Eminent Spine Black / Red Diamond Rattlesnake Lumbar Plating System.*

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 26, 2014

Eminent Spine, LLC
% Linda Braddon, Ph.D.
Secure BioMed Evaluations
7828 Hickory Flat Highway, Suite 120
Woodstock, Georgia 30188

Re: K133194
Trade/Device Name: Black / Red Diamond Rattlesnake Lumbar Plating System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: May 22, 2014
Received: May 28, 2014

Dear Dr. Braddon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K133194

Device Name
Black / Red Diamond Rattlesnake Lumbar Plating System

Indications for Use *(Describe)*
The Eminent Spine Black Diamond Rattlesnake Lumbar Plating System is indicated for use via a lateral / anterolateral surgical approach above the great vessels in the treatment of the thoracolumbar spine (T1-L5). The Eminent Spine Red Diamond Rattlesnake Lumbar Plating System is indicated for use via an anterior surgical approach below the bifurcation of the great vessels in the treatment of the lumbosacral (L1-S1) spine. The Diamond Rattlesnake System is intended to provide temporary stabilization as an adjunct to fusion using a lateral approach in skeletally mature patients for the treatment of the following acute and chronic instabilities and deformities: degenerative disc disease (DDD, defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), pseudarthrosis, spondylolysis, spondylolisthesis, deformity (scoliosis, kyphosis, and or lordosis), spinal stenosis, fracture (including dislocation and subluxation), tumor, or failed previous spine surgery.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Anton E. Dmitriev, PhD

Division of Orthopedic Devices

PSC Publishing Services (301) 443-6740 EF

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."